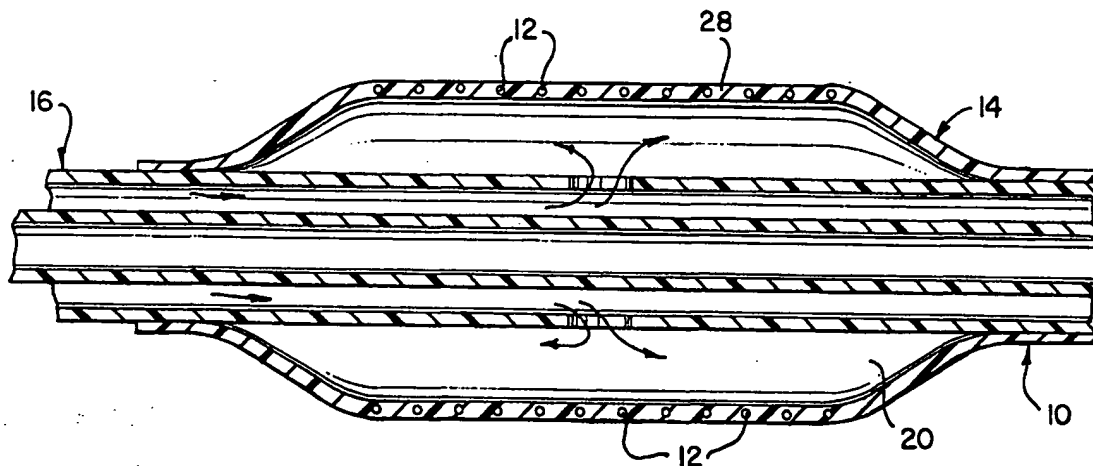


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61M 29/02, A61F 2/06</b>	<b>A3</b>	<b>(11) International Publication Number:</b> <b>WO 99/16500</b> <b>(43) International Publication Date:</b> 8 April 1999 (08.04.99)
<b>(21) International Application Number:</b> PCT/US98/20566 <b>(22) International Filing Date:</b> 30 September 1998 (30.09.98) <b>(30) Priority Data:</b> 60/060,630 1 October 1997 (01.10.97) US <b>(71) Applicant:</b> C. R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US). <b>(72) Inventor:</b> GRANTZ, Stephen; 3 Michelle Avenue, Pelham, NH (US). <b>(74) Agents:</b> DURKIN, Tracy-Gene, G. et al.; Sterne, Kessler, Goldstein & Fox P.L.L.C., Suite 600, 1100 New York Avenue, N.W., Washington, DC 20005-3934 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>  <b>(88) Date of publication of the international search report:</b> 17 June 1999 (17.06.99)

**(54) Title:** DRUG DELIVERY AND GENE THERAPY DELIVERY SYSTEM**(57) Abstract**

A drug or gene therapy solution delivery system including a balloon catheter having a balloon associated with a distal end of the catheter, the balloon having an exterior surface and comprising: a plurality of microencapsulated spheres containing a drug or gene therapy solution, the microencapsulated spheres being disposed about the exterior surface of the balloon so as to rupture upon application of a predetermined pressure to the balloon. In one embodiment, the microencapsulated spheres are encapsulated in a coating applied to the exterior surface of the balloon. In another embodiment, the microencapsulated spheres are extruded in the balloon. In yet another embodiment, the invention provides a drug or gene therapy solution delivery system including a stent, the stent comprising: a plurality of microencapsulated spheres containing a drug or gene therapy solution delivery solution, the microencapsulated spheres being disposed about the exterior surface of the stent so as to rupture upon radial expansion of the stent by a predetermined amount.

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**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61M29/02 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 102 402 A (DROR) 7 April 1992 see the whole document ---	1-3 4,5
X	WO 95 03083 A (BOSTON SCIENTIFIC) 2 February 1995 cited in the application see claims 1,3,26; figures ---	1-5
A	US 5 199 951 A (SPEARS) 6 April 1993 see claims 1,24; figures ---	1
A	WO 94 21320 A (ADVANCED CARDIOVASCULAR SYSTEMS) 29 September 1994 see page 5, line 30 - page 6, line 26; figures ---	1,4
A	EP 0 747 069 A (COOK) 11 December 1996 see claims 1,7,15; figures ---	4,5
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

30 March 1999

Date of mailing of the international search report

12.04.1999

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	WO 98 34669 A (ENDOVASC) 13 August 1998 see page 5, line 12 - page 6, line 15; figures	4,5
P,A	WO 98 34564 A (INTRAVASCULAR) 13 August 1998 see page 9, paragraph 5	4,5

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 98/20566

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 6,7  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery**
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

A drug delivery system including a balloon catheter having a balloon, wherein a plurality of microencapsulated spheres containing a medicament are disposed about the exterior surface of said balloon.

2. Claims: 4,5

A drug delivery system including a stent capable of radial expansion, said stent comprising a plurality of microencapsulated spheres containing a medicament, wherein the microencapsulated spheres are disposed about the exterior surface of said stent.

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